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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,118	07/30/2003	Magnus Bolmsjo	211.312	8332
28785	7590	05/20/2004	EXAMINER	
JOHN R LEY, LCC 5299 DTC BLVD, SUITE 610 GREENWOOD VILLAGE, CO 80111			BOGART, MICHAEL G	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,118

Applicant(s)

BOLMSJO ET AL.

Examiner

Michael G. Bogart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-12 and 17-33 is/are allowed.
- 6) ☒ Claim(s) 1, 13 and 16 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/28/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

In the preliminary amendment to the specification of 28 October 2003, applicants updated the issued status of US 6,626,876 B1 and deleted the corresponding patent application number and filing date. The deleted information should be reincorporated into the first paragraph of the specification.

At page 6, line 15, replace "bode" with --body--.

Claim Objections

Claims 2, 3 and 28 are objected to because of the following informalities:

Claim 2 recites the limitation "the drainage body" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the tube-shaped body" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 recites the limitation "the cavity" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is suggested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. §§ 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 13 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Aldrich *et al.* (US 5,489,269 A).

Regarding claim 1, Aldrich *et al.* teach a method for the insertion of a device (10) for the drainage of the bladder through the body's own opening outside of the human body, wherein

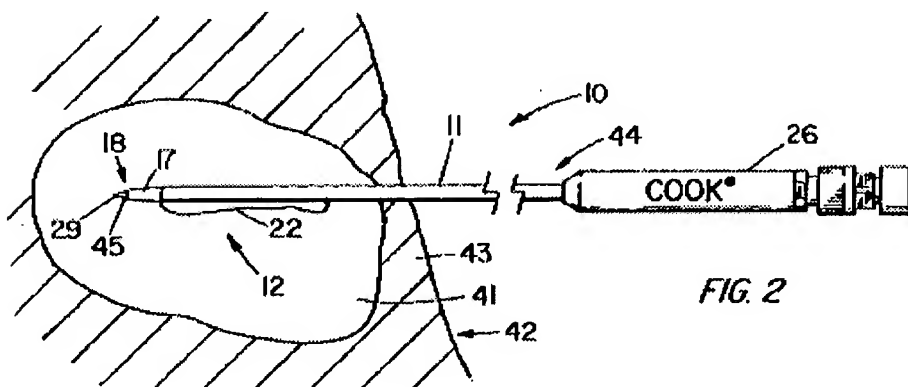
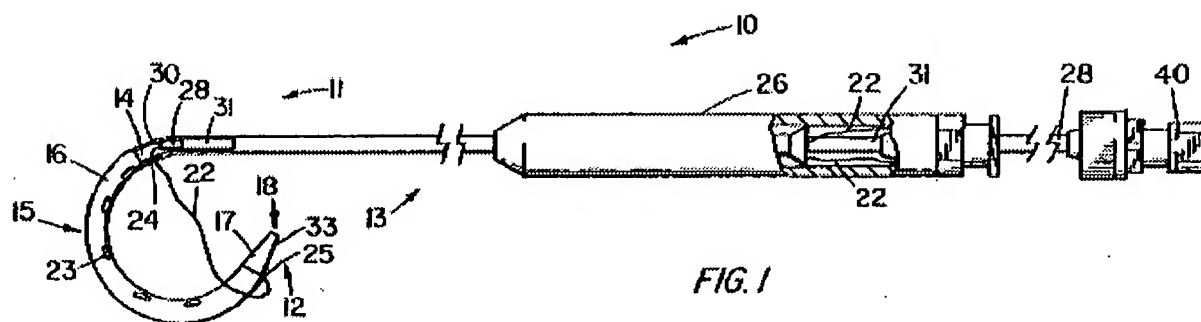
a tube-shaped body (11) extends from a first contracted position to an extended second position and is inserted into a longish tube-shaped introducing member (26),

the tube-shaped introducing member (26) is inserted through the body opening, so that an end piece of the tube-shaped body passes into the bladder,

the tube-shaped body (11) is pushed out of the tube-shaped introducing member (26) and into the bladder during the course of which the return of the tube-shaped body (11) to the first

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contracted position occurs completely within the bladder and in the course of which the placement of a thread (22) extends outside of the body opening that is attached to the tube-shaped body (11)(col. 3, line 66-col. 4, line 50)(see Figs. 1 and 2, below).



Aldrich *et al.* do not expressly disclose that the body opening which the device (10) is inserted to is a urethra. Aldrich *et al.* does disclose a device designed to be anchored in a bladder (col. 6, line 66-col. 4, line 2). Because the only naturally occurring route to a bladder from outside of a patient is via the urethra, the disclosure as a whole implies that in order to insert the device into a bladder, it must first be routed through the urethra.

Implied limitations in the prior art may be applied against the instant invention for the purposes of determining nonobviousness. "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences

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which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968); *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976). See MPEP § 2144.01.

Regarding claim 13, Aldrich *et al.* teach an introducing (26) apparatus for the insertion of an elongated urine drainage apparatus (10) into a bladder, the drainage apparatus (10) comprising a tube shaped body (11) that has a first contracted position (Fig. 1) and a second extended position (Fig. 2) and a thread (22) attached to one end (18), the introducing apparatus (26) comprising:

a flexible guide (31) that has a length sufficient to extend from an exterior opening of a body through to the bladder, and

the flexible guide (31) has a transverse dimension to fit within the tube shaped body (11) when the body (11) is in the extended position, and

the flexible guide (31) has sufficient rigidity to temporarily hold the tube-shaped body (11) in the extended position when the flexible guide (31) is inserted in the body (11)(col. 4, lines 29-50).

Regarding claim 16, Aldrich *et al.* teach that the flexible guide (31) comprises a grip (26, 44) at one end to facilitate the insertion of the drainage apparatus (10) through the body opening (col. 4, lines 51-66).

Allowable Subject Matter

Claims 2-12 and 17-33 are allowed.


Claims 14 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (703) 605-1184. The examiner can normally be reached Monday-Friday.

In the event the examiner is not available, the examiner's supervisor, John Calvert may be reached at phone number (703) 305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 746-3380 for informal communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.


Michael Bogart
14 May 2004


JOHN CALVERT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700